UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,194	12/01/2003	John Fitzgerald Kokai-Kun	7787.0061-00	1338

28765 7590 09/22/2005

WINSTON & STRAWN LLP
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,194	KOKAI-KUN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-30 and 39-58* is/are pending in the application.

4a) Of the above claim(s) *39-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/04;3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

500

DETAILED ACTION

Claims 18-30 and 38-58 are pending.

Election/Restrictions

1. Claims 38-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 27, 2005.

2. Applicant's election with traverse of Group III, claims 18-30 in Paper No. dated June 27, 2005 is acknowledged. The traversal is on the ground(s) that examination of claims 18-30 and 38-58 cannot constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term Adistinct≅ is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I and III are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Compositions of antibodies and the therapeutic treatment of

human or mammalian patients are art recognized divergent subject matter, which is at least characterized based upon differing class and subclass designations. In the instant case a burden has been established in showing that the inventions of Groups I and III are classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example antibodies are utilized in immunoaffinity purification of antigens, incorporated into diagnostic kits, and can be formulated and used in a method of treating or preventing invention . Additionally, it is submitted that the inventions of Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP э 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate

in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ∋ 103(b),≅ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ∋ 804.01.

Claim Objections

3. Claims 26-27 and 29-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 26-27 and 29-30 depend directly or indirectly from independent claim 18 and recite claim limitations directed to a staphylococcal infection while the composition of claim 18 is directed to an antibody composition. How claims 26-27, and 29-30 further limit the structural components or characteristics of claim 18 is unclear and therefore are not further limiting of claim 18. While the composition of claim 18 serves to alleviate or block infection the compositions of claims 26 –27 and 29-30 set forth compositions that result in staphylococcal infection that is localized, systemic or foreign body contamination which is a combination of claim limitations that is broader in scope than claim 18 which alleviates or blocks infection and the compositions of claims 26-27 and 29-30 appear to broaden the scope to permit infection of several types and do not block nor alleviate infection. Claims 26-27 and 29-30 are not further limiting of independent claim 18.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (WO98/57994) as evidenced by (PG Pub 20030228322A1).

6. Fischer et al disclose the instantly claimed invention directed to:

(Instant claims 18, 26-27) Compositions of antibodies that bind to WTA, wherein the antibodies bind to lipoteichoic acids (surface exposed (see page 9, paragraph 2, last sentence) that are teichoic acids in the wall of staphylococcal strains and species (see page 9, paragraphs 1-2 "The basis of the binding is the presence of LTA exposed on the surface of the cell wall of Gram Positive bacteria" "Teichoic acids are polymers of either glycerol phosphate or ribitol phosphate with various sugars, amino sugars and amino acids as substituents. Although the lengths of the chains and the nature and location of the substituents vary from species to species and sometimes between species, in general teichoic acids make up a major part of the cell wall. The teichoic acids related to this invention are lipoteichoic acids which are teichoic acids made up of glycerol phosphate which is primarily linked to a glycolipid" Fischer Figure 1) and alleviate or block staphylococcal colonization (see page 21, paragraph 2 "staphylococcal infection"; see page 24 "S.epidermidis, strain Hay"; S. aureus 5 and S.sureus-8, see page 27, bottom of page and page 28, paragraphs 1-2) upon administration to a patient (see Figure 4 "enhancement of survival in adult mice infected with coagulase negative staphylococci"; therapeutically effective amount (see page 20, paragraph 4 "Indeed, combination therapy with other antibodies is expressly contemplated within the invention.).

Instant claim 19: polyclonal antibodies (see page 16, paragraph 4, line 4)

Instant claim 20: monoclonal (see page 14, paragraphs 2-4; page 16, paragraph 4, line 4-5).

Instant claim 21: monoclonal antibodies with non-identical amino acid sequences (see antibodies with homologous sequences (see page 18, paragraph 4; page 19, paragraphs 1 and 3 "form the basis of antibody "derivatives"; see claims 21-22)

Instant claim 22: chimeric antibody (see page 18, paragraphs 2-3).

Instant claim 23: humanized antibody (see page 17, paragraph 4 through to page 18, paragraph 1 "together with regions of human antibodies).

Instant claim 24: human antibody (see page 20, paragraph 3, lines 7-8 "human"; page 12, "Directed Human Immune Globulin).

Instant claim 25: fragment of antibodies (see page 17, paragraph 2 ; "Fab, Fab', F(ab')2 and SFv "; see page 21, paragraph 1).

Instant claim 28-30: pharmaceutically acceptable carrier (see page 19, paragraph 4; page 20, paragraphs 1-2)

Inherently the lipoteichoic antibodies of Fischer et al anticipate the instantly claimed invention as now claimed would also specifically bind to the teichoic acid of at least S.epidermidis in light of evidence that PG Pub 20030228322 provides in stating that S.epidermidis teichoic acid and lipoteichoic acid have the same glycerol phosphate backbone.(see 20030228322, paragraph [0008]).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Fischer (US Pat. 5,571,511) is cited to show compositions of polyclonal immunoglobulin produced to a S.epidermidis cell lysate that comprised polysaccharides (see col. 7, lines 43-56; and col. 8, lines 55-57 "reduced the number of bacteria").
9. Jacob et al (1987) is cited to show antibodies to teichoic acids of Staphylococcus aureus.
10. US Pat. 5,367,058 is cited to show a phophorylcholine binding antibody that is a component of wall teichoic acids for Streptococcus strains (see all claims).
11. Lee (US Pat. 6,365,156) is cited to show anti-
12. Lees (US Pat. 6,585,973) is cited to show anti-phophorylcholine protective antibodies (see Table 5).
13. US Pat. 6,203,997 is cited to show a diagnostic kit that comprises anti-teichoic acid antibodies (see claims 8-13).
14. US Pat. 4250262 is cited to show an antiserum directed to the polyglycerol phosphate backbone of teichoic acid (DE-1 preparation of antibodies).
15. US Pat. 5139933 is cited to show Listeria cell wall teichoic acid monoclonal antibodies.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600